

**REMARKS UNDER 37 CFR § 1.111**

**Formal Matters**

Claims 1-20 and 33-53 were examined and rejected. Claims 2-32 were withdrawn from consideration in response to an election/restriction of claims.

By this Amendment, claims 21- 32 have been cancelled, claims 1, 9, 12, 15, 18, 40 and 48-54 have been amended and claim 54 has been added.

Claims 21- 32 are canceled without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. Applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim.

As there was no original claim 49, claims 50-54 have been renumbered as claims 49-53. As such, the newly added claim is numbered as 54. Claims 15 and 18 have been amended to depend from new claim 54.

Support for the claim amendments and for the newly added claims is found in the original claims and throughout the specification and the drawings. Accordingly, no new matter is added by these amendments.

Claims 1-20 and 33-54 are pending after entry of the amendments set forth herein.

Applicants respectfully request entry of the amendments herein and reconsideration of the application in view of the amendments and remarks made herein.

**Election/Restriction**

In the Office Action, the Examiner required election of one of the following groups of claims:

Group I: Claims 1-20 and 33-53, drawn to a sampling device having a skin-piercing member, an electrochemical cell and a hydrophilic transfer medium as well as the associated method of use.

Group II: Claims 21-32, drawn to an array of micro-needles having two layers of conductive material.

Applicants hereby confirm the provisional election of Group I, claims 1-20 and 33-53, with traverse. As stated in the MPEP §803, if search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. It is Applicant's position that it would not be unduly burdensome to perform a search on all of the pending claims. Accordingly, Applicants traverse the restriction requirement.

### **Double Patenting Rejections**

Claims 1-20, 33-39 and 49-53 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,501,976. Applicant respectfully submits that the claims of the cited patent and of the subject application are patentably distinct as the respective claimed devices are structurally distinct from each other. The cited patent claims cover a device having concentrically spaced or coaxially aligned electrodes and which electrodes are either housed within a micro-needle or form the micro-needle or the like. In contrast, the subject pending claims are directed to a device and method of using the same where the electrodes are distinct structures from the micro-needle (e.g., in certain embodiments the micro-needle extends transversely from one of the electrodes) and/or the electrodes are not concentrically spaced or coaxially aligned with each other. As such the claims of the subject application are not obvious in view of those of U.S. Patent No. 6,501,976. Accordingly, Applicant's respectfully request withdrawal of this rejection.

Claims 1-8, 20 and 33-53 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent Application Serial No. 09/879,146. While Applicant does not acquiesce to the validity of the rejection, Applicant hereby submits the accompanying Terminal Disclaimer with respect to U.S. Patent Application Serial No. 09/879,146.

Claims 1-8, 20 and 33-53 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-57 of U.S. Patent Application Serial No. 09/878,742. Applicant respectfully informs the

Examiner that a Notice of Allowance has been received for the '742 application having only renumbered claims 1-12 directed to a device having a micro-needle and an electrochemical cell comprising inner and outer electrodes having cylindrical configurations and spaced from each other in a co-axial relationship, and where the micro-needle is formed at least partially by the outer electrode. In contrast, the subject pending claims are directed to a device and method of using the same where the electrodes are distinct structures from the micro-needle (i.e., they do not form any part of the micro-needle or piercing structure) and/or the electrodes are not cylindrical or coaxially aligned with each other. As such the claims of the subject application are not obvious in view of those of U.S. Patent Application Serial No. 09/878,742. Accordingly, Applicant's respectfully request withdrawal of this rejection.

Applicants also wish to inform the Examiner that a divisional application claiming priority to the '742 application was filed on September 23, 2003. A serial number has not yet been received for this divisional application.

Claims 9-19 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims 1-39 of U.S. Patent Application Serial No. 09/878,742 in view of Joseph (U.S. Patent No. 5,161,532). For the reasons discussed above, the claims of the subject application are not obvious in view of those of U.S. Patent Application Serial No. 09/878,742. As Joseph is cited solely for its teachings related to porous electrodes, its combination with the '742 application does not make obvious the subject matter of claims 9-19. Accordingly, Applicant respectfully request withdrawal of this rejection.

### **Rejections Under 35 U.S.C. §102**

Claims 1-2, 5-8, 20 and 33-53 were rejected under 35 U.S.C. §102(b) as being anticipated by Gough (U.S. Patent No. 4,671,288).

The present invention as claimed in claims 1-2, 5-8 and 20 provides for a planar electrode. Claims 33-39 provide for a system comprising a device according to claim 1. Claims 48-53 provides for a method of using the system of claim 33. Claims 40-47 provide for a method of using a micro-needle comprising an open distal end and transferring the absorbed constituents through a hole in a conductive material. In

contrast, Gough does not disclose, suggest or teach a device having a planar electrode and/or a micro-needle with an open distal end and/or a conductive material having a hole there through.

For at least these reasons, claims 1-2, 5-8, 20 and 33-53 are patentable in view of Gough. Accordingly, Applicant respectfully requests withdrawal of the rejection and allowance of the claims.

### **Rejections Under 35 U.S.C. §103**

Claims 3 and 4 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gough in view of Nitzan (U.S. Patent No. 5,897,522).

As discussed above with respect to the rejection of claim 1, Gough does not disclose, teach or suggest a device having a planar electrode. Nitzan fails to make up for the deficiencies of Gough as Nitzan is cited solely for its teaching relating to use of a natural gel matrix. Accordingly, for at least the reasons described above, the combination of Gough and Nitzan fails to render claims 3 and 4 obvious. Applicants respectfully request withdrawal of this rejection and allowance of the claims.

Claims 9-19 are rejected under 35 U.S.C. §103(a) as being unpatentable over Gough in view of Joseph.

As the dependency of claims 15-19 have been amended to depend from or have a chain of dependency on newly added claim 54, this rejection has been made moot with respect to them.

As discussed above with respect to the rejection of claim 1, Gough does not disclose, teach or suggest a device having a planar electrode. Joseph fails to make up for the deficiencies of Gough as Joseph is cited solely for its teaching relating to use of a porous electrode. Accordingly, for at least the reasons described above, the combination of Gough and Joseph fails to render claims 9-14 obvious. Applicants respectfully request withdrawal of this rejection and allowance of the claims.

### **Newly Added Claims**

Newly added claim 54 provides for a device comprising a first electrode having pores therein; a second electrode positioned substantially parallel to the first electrode; an

electrochemical cell defined between the first and second electrodes; at least one hollow micro-needle extending substantially transverse to the first electrode wherein at least one pore of the first electrode is axially aligned with the micro-needle, the micro-needle having an open distal end for accessing biological fluid; and a hydrophilic material contained within at least a portion of the at least one hollow micro-needle and within the electrochemical cell.

None of the cited references or combinations thereof disclose, teach or suggest the above combination of limitations. Accordingly, claim 54 and claims 15-19 which are dependent on or have a chain of dependency on claim 54 are allowable, and such allowance is respectfully requested.


### **Conclusion**

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number LIFE-019.

Respectfully submitted,  
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Date: 10/7/03

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